REMARKS

The Amendment, filed in response to the Office Action mailed August 12, 2010, is believed to fully address all issues raised in the Action. A favorable reconsideration on the merits and allowance of the application is respectfully requested.

Claims Disposition

Upon entry of the current amendment, which is respectfully requested, claims 12-13, 16-19, 20, and 22 are all the claims pending in the application.

Claim 12 is amended herein by clarifying that the method for stabilizing 1,4-dihydroxy-2naphthoic acid comprises reducing "the level of" oxygen. Claims 12 and 13 are amended herein to recite that stabilization occurs via <u>substituting the oxygen with an inert gas, and further conducting a heat treatment on the solution</u>. Support for these amendments can be found in claim 20, which was canceled as a result, and in Example 2 of the present specification.

Claims 15 and 16 are amended to correct dependency and to recite that the oxygen is is "kept" reduced after the heat treatment, for purposes of clarification.

Claim 21 is amended to delete the phrase ~~wherein a part of or all of the processes~~ and recite that the method is carried out <u>partially or entirely</u> under conditions in which the oxygen is reduced. Support for this amendment to claim 21 can be found at page 6, lines 12-15.

No new matter is introduced.

Response to Rejection under 35 U.S.C. § 112

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In the Action, the Examiner takes the position that claim 21 is indefinite because it depends from claim 13 which is directed to two methods, but claim 21 does not state which method is being used.

Further, the Examiner states that claim 21 recites the limitation "the processes" and there is insufficient antecedent basis for this limitation.

In response and without acquiescing to the merits of the rejection, Applicants amend claim 21 as discussed above to better clarify the method.

Applicants respectfully submit that the present amendments render moot the rejection and, accordingly, request the Examiner to withdraw the indefinite rejection of claim 21.

Claim Rejections under 35 U.S.C. §102 & §103 Based on Sato

Claims 12-15, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Sato et al. WO 03/016544 (US 7,374,915 is relied upon for translation; ("Sato") as evidenced by Sukajang et al. entitled "Effects of sodium ascorbate and drying temperature on active protease of dried ginger" ("Sukajang").

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sato et al. US 7,374,915 in view of Davies et al., 2,104,415.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. US 7,374,915 in view of Mizandjian et al. US 4,766,001.

Applicants respectfully traverse.

The instant specification discloses that as a result of intensive studies carried out with the aim of achieving the aforementioned object, it is confirmed that 1,4-dihydroxy-2-naphthoic acid (DHNA) is apt to be oxidized, and particularly, heat treatment in the presence of oxygen easily oxidizes DHNA and considerably reduces content thereof in a liquid.

Accordingly, Applicants unexpectedly found that reduction of the DHNA content can be significantly inhibited without adding a stabilizing agent by reducing the dissolved oxygen in a

liquid before heat-treating the liquid containing DHNA. The invention has been accomplished based on these new findings.

Furthermore, Applicants submit that the method of Sato is very different from the present method, and cannot be said to anticipate the present claims. The present invention is best exemplified by Example 2 of the specification. In Example 2, a mixture of raw materials (80% by weight of commercial milk, 2% by weight of skim milk powder and 14.5% by weight of water) not including 1,4-dihydroxy-2-naphthoic acid was bubbled with nitrogen gas. Dissolved oxygen concentration of the mixture was about 10 ppm before the bubbling, but reduced to less than 1 ppm after bubbling with nitrogen gas.

A DHNA-containing composition having a DHNA content of 40 μg/ml prepared in accordance with the Example 2 of WO 03/016544 A1 was added in an amount of 1.5% by weight to the mix pasteurized by heating at 95°C for 5 minutes by a batch system and then cooled to 43°C. Each of the aforementioned bulk starters was inoculated therein in an amount of 1% by weight, and then aseptically filled and sealed in a sterilized non-barrier polystyrene container (manufactured by Asahi Plastics Co., Ltd.). The bubbling of nitrogen was continued until inoculation of the starters and, after the filling, the fermentation was carried out at 43°C for 4 hours.

This Example is depicted in the flow chart below. As can be seen in the flow chart, it is an essential point of the present invention to substitute oxygen with nitrogen gas during the "heating treatment step" comprising compounding, sterilization and immediately before filling into a container.

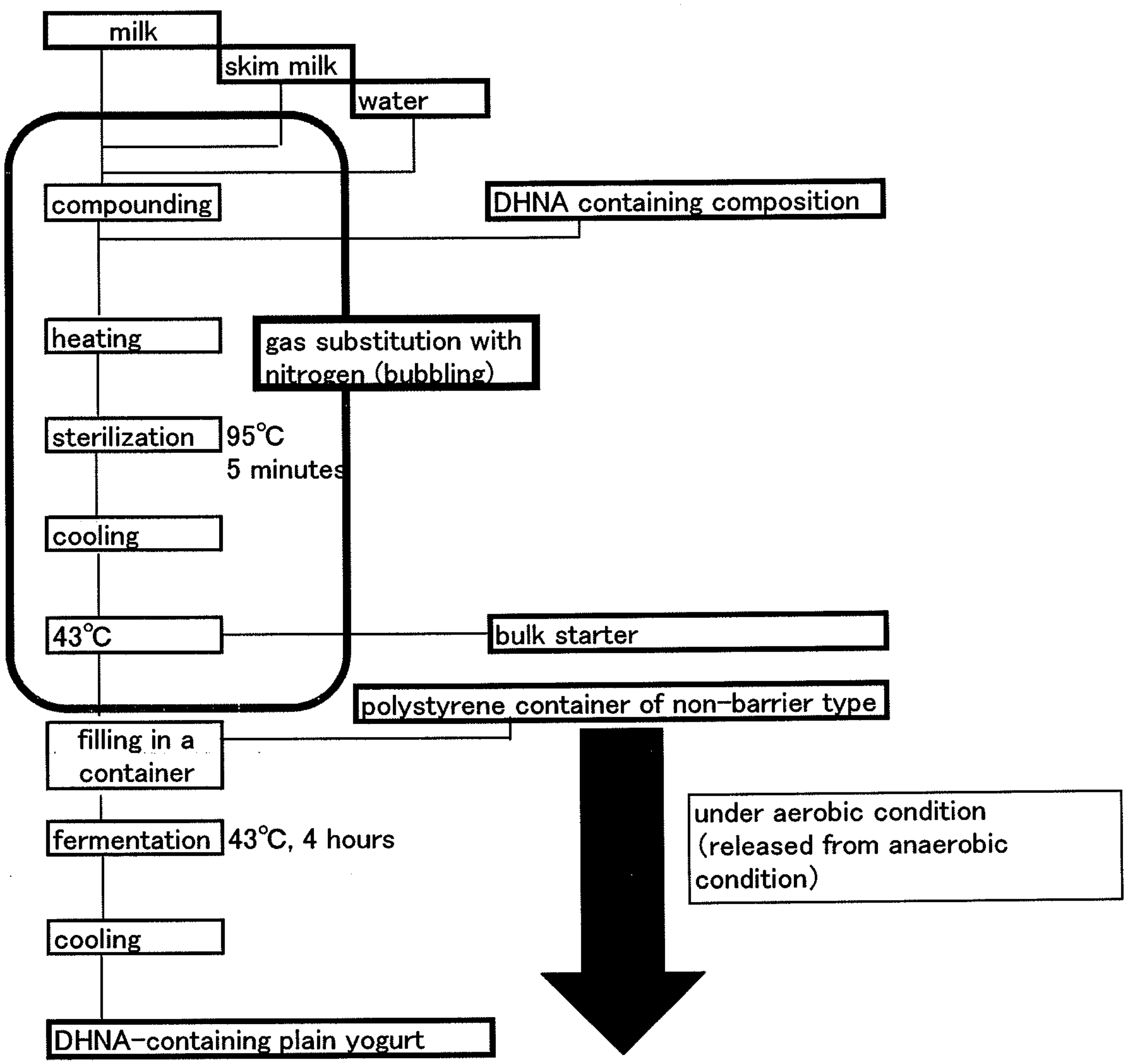


Fig. 1: Flow Chart of the Present Invention (Example 2)

After the heating treatment, there is a step of aseptically filing the composition into a polystyrene cup (manufactured by Asahi Plastics KK) of a non-barrier type. "Non-barrier type" means a common polystyrene cup which is not subjected to an "oxygen barrier." Therefore,

oxygen is not permeated into the inside of the cup and dissolved oxygen is reduced only when a heating treatment is carried out.

Method of Sato

Sato discloses food, drink or pharmaceuticals containing 1,4-dihydroxy-2-naphthoic acid, and as an example of manufacturing a food containing said 1,4-dihydroxy-2-naphthoic acid, Sato discloses a method wherein sodium ascorbate is added to a product cultured under an anaerobic condition followed by heating. *See* Example 9.

However, Sato discloses a process for the production of 1,4-dihydroxy-2-naphthoic acid synthesized by an organic chemical synthesis and has been difficult to use in food, drinks, and pharmaceuticals produced using microorganisms. Sato discloses that the "culture" for producing the 1,4-dihydroxy-2-naphthoic acid is carried out "under an anaerobic condition." However, in Sato, although ascorbic acid (which is an antioxidant) is added to said "culture solution," only small amounts of said "culture solution" wherein oxygen concentration is reduced is added as an additive to the "solution for food or drink, etc." The Sato solution is not subjected to a deoxidizing treatment, prior to sterilizing. *See* Example 9.

Differences Between the Present Method and the Method of Sato

Although the present method and the method disclosed in Sato both utilize 1-4-dihydroxy-2-naphthoic acid in food, these methods are very different from each other in several aspects: the oxygen dissolved in the presently claimed solution for food or drink containing 1,4-dihydroxy-2-naphthoic acid is reduced (hereinafter, it will be referred to as "the difference a"); that reducing of the oxygen in said solution is conducted by substituting inert gas (hereinafter, it will be referred to as "the difference b"); and the presently claimed solution for food or drink

wherein the oxygen dissolved in the solution is reduced is subjected to a heating treatment (hereinafter, it will be referred to as "the difference c").

To begin with, since the present method and the Sato method are entirely different in view of their technical idea, the Examiner's assertion that the present invention is obvious based on the Sato method is ill-founded.

Applicants confirm the above discussed differences in flow chart, below.

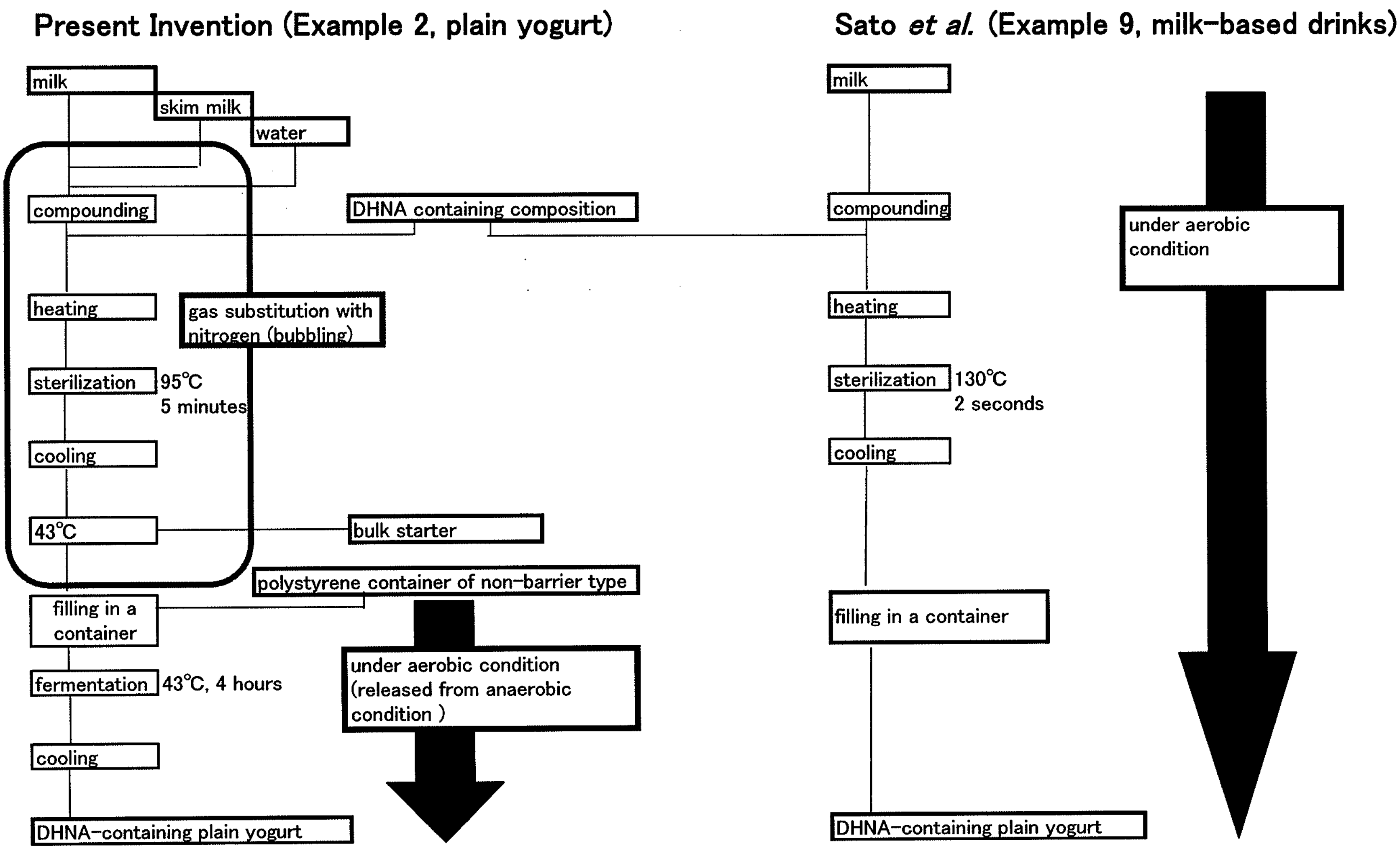


Fig. 2 Flow Chart of Difference between the Present Invention and Sato *et al.*

Difference "a"

In the present method, oxygen dissolved in the solution for food or drink containing 1,4-dihydroxy-2-naphthoic acid is reduced, whereas in the Sato method, culture of 1,4-dihydroxy-2-naphthoic acid is conducted under an anaerobic condition and further, sodium ascorbate is added to said "culture solution" and a small amount of the resulting "culture solution of 1,4-dihydroxy-2-naphthoic acid" is added to a solution for food or beverage (raw milk without deoxidizing treatment) as an additive, as illustrated in Example 9 of Sato.

When culture solution containing sodium ascorbate is added to the food in the Sato method, the deoxidized state caused by the anaerobic culture condition and by addition of sodium ascorbate results in a solution that is no longer in a "deoxidized state." Thus, in Example 9 of the Sato, the final amount of 1,4-dihydroxy-2-naphthoic acid is 11 μg/100 ml and the added amount of sodium ascorbate in the food (raw milk without the deoxidizing treatment) to which a culture solution containing sodium ascorbate is added is very small. The amount of sodium ascorbate added in Example 9 of Sato is as very small at 0.008875% (w/v) in the final product [0.5 x 177.5/10000 = 0,008875% (w/v)] and it is thus apparent that the solution is no longer in a "deoxidized state."

Difference "c"

In the present method, after reducing the oxygen dissolved in the solution for food or drink containing 1,4-dihydroxy-2-naphthoic acid, the solution is further subjected to a heat treatment.

According to the present method, not only is the oxygen dissolved in the solution for food or drink containing 1,4-dihydroxy-2-naphthoic acid reduced, but in addition, the solution is

subjected to heat treatment by which stabilization of 1,4-dihydroxy-2-naphthoic acid contained in the solution for food or drink is achieved. Thus, when the oxygen dissolved in the solution before the heating treatment is first reduced, it is possible to achieve the stabilization of 1,4-dihydroxy-2-naphthoic acid contained in the solution for food or drink even if the concentration of oxygen dissolved in the solution rises after the heating treatment. *See* Figs. 1 and 2; storage period is eight weeks in Fig. 2. This effect is specific to the present invention.

FIG. 1

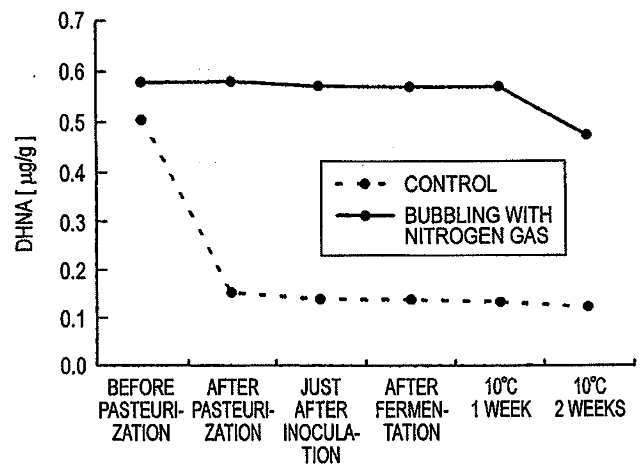
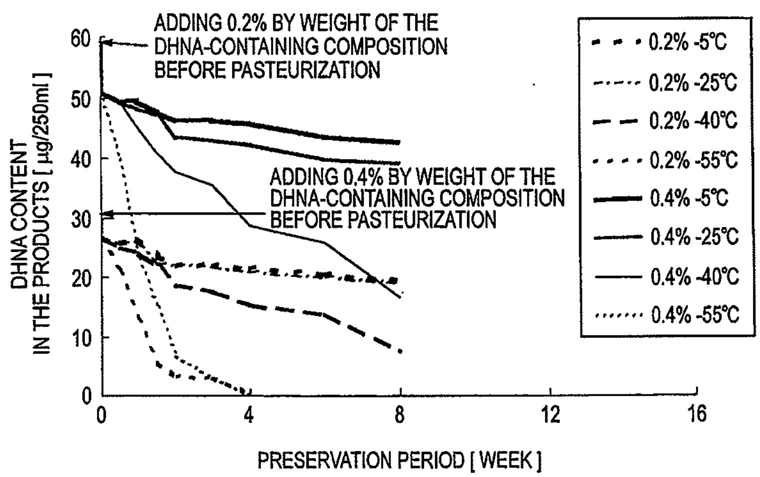


FIG. 2



On the contrary, in Sato, the deoxidized state disappears at the stage where a culture solution containing sodium ascorbate is added to raw milk. Therefore, it is apparent that when a solution for food or drink containing 1,4-dihydroxy-2-naphthoic acid (raw milk to which the culture solution containing sodium ascorbate is added) is subjected to a heating treatment, concentration of oxygen dissolved in the solution has not been reduced.

Accordingly, it is apparent that addition of sodium ascorbate to a culture solution of 1,4-dihydroxy-2-naphthoic acid as in Sato is not intended to stabilize 1,4-dihydroxy-2-naphthoic acid which is most apt to be affected by heating. It is further apparent that in Sato, the deoxidized state disappears when a culture solution of 1,4-dihydroxy-2-naphthoic acid containing sodium ascorbate is added to raw milk. Therefore, stabilization of 1,4-dihydroxy-2-naphthoic acid contained in the solution for food or drink after heating cannot be achieved in Sato.

Difference "b"

In the present invention, substitution of dissolved oxygen with inert gas is conducted to reduce the oxygen dissolved in the solution to a level as low as 5 ppm (Examples 2 and 3). In

the present Amendment, Applicants amend claim 1 to recite subject matter of claim 20, to recite that the oxygen dissolved in said solution is reduced by substituting it with an inert gas.

In this connection, the Examiner acknowledges that Sato does not teach the use of an inert gas to reduce oxygen. Mizandjian is then cited by the Examiner in this regard. According to the Examiner, Mizandjian discloses a process for treating a food or biological liquid with a gas, such as nitrogen and carbon dioxide, to dissolve oxygen (abstract). *See* Office Action, at page 5, second paragraph.

Applicants respectfully disagree with the Examiner's characterization of Mizandjian.

Mizandjian relates to a process for deoxygenating or carbonating a food or liquid product having an initial dissolved oxygen concentration between 9 mg/l and 12 mg/l, comprising injecting at least one gas selected from the group consisting of nitrogen and carbon dioxide into a current of the food or biological liquid product thereby to form a gas/liquid emulsion. The emulsion is introduced into a storage vessel.

Applicants submit that Mizandjian does not disclose reducing the level of oxygen dissolved in a solution by substituting the oxygen dissolved in said solution with an inert gas. In view of the above, Applicants submit that he references cited by the Office, either alone or in combination, do not teach all and every elements of the currently amended claims and request withdrawal of the rejections under 35 U.S.C. §102 & §103 based on Sato.

For the reasons discussed above, it is believed that the rejections are not sustainable and Applicants respectfully request the rejections be withdrawn.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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